

Please cancel claims 4-13, 16-18 and 20-27.

REMARKS

Reconsideration and withdrawal of the rejections of the claims, in view of the amendments and remarks presented herein, is respectfully requested.

Applicants have added no new matter by their amendments of claims 1, 14 and 28 or their addition of new claim 29. Support for the amendments and new claim may be found throughout the application. In particular, support for the term "aqueous" may be found in original claim 11 and at page 7, line 18 through page 8, line 22. Support for the term "thermoplastic polymer" of claim 1 may be found in original claims 12 and 13 as well as at page 9, line 5 through page 10, line 20. Support for the solvent character given in claim 1 is found at page 12, lines 8-23 and at page 13, line 16 through page 14, line 12. Support for new claim 29 is found at page 8, lines 18-22.

Response to Examiner's Statement about Election

In connection with his comment about the species election, the Examiner asserts that Applicants stated in paper No. 11 that aqueous and non-aqueous carriers are equivalent and that polymeric and non-polymeric matrices are equivalent. The Examiner further stated that the above admission may be used in a rejection under 35 U.S.C. § 103(a) of the other inventions.

Applicants deny that they made such a statement. Applicants also deny that they have made any statement about these carriers and matrices that may be construed as an admission for use in further rejections. To the contrary, Applicants stated in paper No. 11 that the election of species should be modified to require designation of an aqueous or non-aqueous carrier and a polymeric or non-polymeric matrix. Applicants have said the opposite of what the Examiner asserts. Applicants have clearly stated that aqueous and non-aqueous carriers are not equivalent, and that polymeric and non-polymeric matrices are not equivalent. Moreover, Applicants recommended to the Examiner that he issue a species election for these designations rather than for the designations he chose.

Applicants have proceeded with their choice of polymeric matrices and aqueous carriers. The Examiner may wish to make this choice part of a species election. In any event, Applicants reserve their right to prosecute separate patent applications claiming the other combinations of the carriers and matrices.

Claim Rejection, 35 U.S.C. §112

The Examiner rejected claims 6, 17 and 18 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention

Inasmuch as claim 6 has been cancelled and the subject matter of claim 6 eliminated from the present application, this rejection of claim 6 is moot.

Applicants have amended claim 1 to add to it the subject matter of claim 18. Applicants have specified that the water solubility of the organic solvent is no more than about 20% by weight. Applicants submit that this quantification of low water solubility overcomes the rejection. Applicants respectfully request withdrawal of this rejection

Claim Rejection, 35 U.S.C. § 103

The Examiner rejected claims 1-24, 27 and 28 under 35 U.S.C. § 103(a) as being unpatentable over WO 95/27481 (hereinafter application '481).

Applicants respond that application '481 does not disclose their invention as claimed in the amended claims.

Application '481 generally discloses a liquid delivery composition containing (a) a liquid delivery system and (b) a controlled release component. (See page 4, lines 30-34 of application '481). The liquid delivery system includes a biocompatible polymer and an organic solvent. (See page 5, lines 10-15). The controlled release component may be a microstructure, macrostructure, conjugate etc. (page 9, lines 12-page 10, line 7).

In the specific citation made by the Examiner, the controlled release component is a liposphere. A liposphere, according to application '481, is a solid, water-insoluble microparticle having a layer of phospholipid embedded on its surface. Its core contains either a solid active agent or an active agent that is dispersed in an inert solid. (See the Examiner's citation at page 12, lines 29-37.) Note that the liposphere does not contain an aqueous core in contrast to the Examiner's assertion.

Irrespective of whether such lipospheres contain solid or aqueous cores, they are solid, hollow spheres of phospholipids and/or other materials. In other words, they are solid particles. In contrast, the claims as amended recite an emulsion or dispersion of (a) the bioactive agent in an aqueous medium and (b) a solution of thermoplastic polymer and organic solvent having low water solubility. The continuous phase of this emulsion or dispersion is the polymer/organic solvent solution. The discontinuous phase of this emulsion or dispersion is the agent-in-aqueous medium. This discontinuous phase is not made up of solid particles. The aqueous micelles of this discontinuous phase do not have shells of solid material and they are not solid hollow spheres. The aqueous micelles are microdroplets of the aqueous medium with agent.

Application '481 does not disclose or suggest such an emulsion or dispersion. Application '481 discloses that when its system of thermoplastic polymer and organic solvent contacts water, the polymer coagulates. (See page 18, lines 3-18 of application '481.) Based upon this disclosure, one would expect that the presently claimed emulsion or dispersion would instantly set up or coagulate. However, it does not.

As shown by Example 1 of the present application, when an organic solvent of low water solubility is employed, an emulsion or dispersion that can be injected is produced. In contrast, as shown by Example 2 of the present application, when an organic solvent of high water solubility is employed, the resulting combination immediately coagulates as Application '481 indicates.

For this reason, Applicants submit that their claims as amended are patentable over Application '481. Application '481 leads one of skill to conclude that he would not be able to form a useful emulsion of an aqueous medium and a liquid delivery system of a thermoplastic polymer and organic solvent.

CONCLUSION

On the basis of the preceding arguments it is respectfully submitted that the pending claims are in condition for allowance. Reconsideration and an early allowance is respectfully requested.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, Washington, D.C. 20231, on this 7th day of February, 2001.

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